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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,904	08/30/2001	Robert A. Drazen	59704	8172

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EXAMINER	
BLECK, CAROLYN M	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,904	DRAZEN, ROBERT A.	
	Examiner	Art Unit	
	Carolyn M. Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *31 August 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 30 August 2001. Claims 1-28 are pending. The IDS statement filed 30 August 2001 has been entered and considered. This application claims the benefit of provisional application 60/229,266 filed 31 August 2000.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirshner (6,322,504) in view of Hennessy et al. (6,277,071).

(A) As per claim 1, Kirshner discloses a system for determining a risk of developing a disease, and the consequences of developing that disease comprising (col. 1 lines 8-14):

(a) a database for storing guidelines related to risk events/ factors of coronary artery disease (Fig. 1, col. 1 lines 15-55, col. 2 lines 16-64, col. 5 lines 20-59);

(b) a medical history database for storing patient information, including responses to questions, for patients (Fig. 1, col. 5 lines 20-30, col. 10 lines 25-39, col. 18 line 25 to col. 19 line 15);

(c) a server computer system having a CPU associated with the databases for collecting a user's physical characteristics, lifestyle, and medical history information via the Internet (Fig. 1, col. 5 lines 1-30, col. 8 lines 48-63, col. 18 line 25 to col. 19 line 15), wherein the server computer processes the user's physical characteristics, lifestyle, and medical history information and generates a risk factor summary based upon the guidelines (Fig. 6A-6T, col. 8 line 47 to col. 13 line 19, col. 19 lines 1-5), wherein the server computer transmits risk factor modification information to the user, wherein the risk factor modification information includes information on how to change the positive and negative risk factors in the risk factor summary, wherein the server also determines a course of action for the user based on the guidelines (col. 17 lines 4-36, col. 18 lines 25-49, col. 20 lines 23-27), wherein the server tracks changes in patient responses to questions about the user's physical characteristics, lifestyle, and medical history information and the positive risk factors for the individual over time, wherein the step of tracking includes advising the user when there has been one of a change and no change in a risk factor, wherein the server compares the user's current risk factors with the user's previous risk factors and gives the patient encouragement or a warning based on the change (col. 17 lines 40-68, col. 18 line 25 to col. 19 line 30).

Kirshner does not explicitly disclose correlating historical patient information and patient compliance information "with the physician's patient treatment plan to generate outcome-specific research data."

Hennessy discloses comparing patient data to guideline values based on the quality plan for the patient to generate a report of the patient population globally, wherein the report displays the percentage of patients meeting their goals (Fig. 16-21, col. 6 line 52 to col. 7 line 8, col. 7 line 62 to col. 8 line 63, col. 9 lines 29-63, col. 10 lines 28-56).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Hennessy within the system of Kirshner with the motivation of allowing the physician to efficiently monitor a chronic disease among the physician's patient population and to determine the success of particular treatments (Kirshner; col. 1 lines 30-50, col. 10 lines 28-55).

(B) As per claim 2, Hennessy discloses the data including health trends (Fig. 16-21, col. 6 line 52 to col. 7 line 8, col. 7 line 62 to col. 8 line 63, col. 9 lines 29-63, col. 10 lines 28-56). As per the recitation of CAD, see Kirshner above in claim 1. The motivation for combining Hennessy within Kirshner is given above in claim 1, and incorporated herein.

(C) As per claim 3, Kirshner discloses the server computer transmitting risk factor modification information to the user, wherein the risk factor modification information

includes information on how to change the positive and negative risk factors in the risk factor summary, wherein the server also determines a course of action for the user based on the guidelines (6A-6T, col. 17 lines 4-36, col. 18 lines 25-49, col. 20 lines 23-27). It is respectfully submitted that the modifications disclosed in Kirshner are based on "trends", where the "trends" are considered to be guidelines.

(D) As per claim 4, Hennessy discloses generating an patient record based on patient information, test results over a period of time, and a quality plan (Fig. 2, col. 6 line 12 to col. 7 line 8). The remaining features of claim 4 have been discussed in claim 1, and are incorporated herein.

(E) As per claim 5, Kirshner discloses generating a course of action including educational information based on guidelines, wherein the information pertains to exercise (Fig. 6A-6T, col. 17 lines 2-37).

(F) As per claim 6, Kirshner discloses the patient information being age, gender, race, height, weight, lifestyle questions such as questions about smoking habits, drinking habits, vitamin intake, and stress, and medical history questions such as questions about blood pressure, diabetes, menopause, ovary removal, hormone replacement, CAD, heart attack, coronary artery bypass surgery, angioplasty, peripheral vascular disease, left ventricular hypertophy, family history, lipid profile, stress tests, and angiograms (col. 18 lines 54-67).

(G) As per claim 7, Hennessy discloses the guidelines pertaining to hypertension, diabetes, cholesterol, obesity, and coronary disease (col. 1 line 50 to col. 2 line 7).

(H) Claims 10-16 repeat claims 1-7, and are therefore rejected for the same reasons as those claim.

(I) Method claims 19-25 and 28 repeat system claims 1-7 and 10-16 as a series of steps rather than as a set of apparatus elements. As the underlying apparatus elements of claims 1-7 and 10-16 have been shown to be fully disclosed by the teachings of Kirshner and Hennessy in the in the above rejections of claims 1-7 and 10-16, it is readily apparent that the system disclosed collectively by Kirshner and Hennessy includes the ability to perform these method steps. As such, these limitations are rejected for the same reasons given above for system claims 1-7 and 10-16, and incorporated herein.

4. Claims 8-9, 17-18, and 26-27are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirshner (6,322,504) in view of Hennessy et al. (6,277,071) as applied to claims 1, 10, and 19, and further in view of Evans (5,924,074).

(A) As per claims 8-9, 17-18, and 26-27, Kirshner discloses a pharmacological therapy chosen by a user (col. 17 lines 20-35). Hennessy discloses a plan having medication

information (Fig. 21). However, Kirshner and Hennessy fail to expressly disclose a medication database wherein a physician's treatment plan includes contraindications. Evans discloses a reference database having medication data, wherein a contraindication is indicated on a patient record (Fig. 13, 21, col. 12 line 65 to col. 13 line 35). At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Evans within the method and system taught collectively by Kirshner and Hennessy with the motivation of allowing a healthcare provider access to a patient's record to properly treat the patient (Evans; col. 2 lines 20-64).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied prior art teaches expert system for generating guideline-based information tools (5,574,828), system and method of generating prognosis and therapy reports for coronary health management (5,724,580), therapeutic behavior modification program, compliance monitoring and feedback system (6,039,688), and method and system for analyzing and presenting NMR lipoprotein based risk assessment results (6,576,471).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (571) 272-

6767. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(571) 273-8300	[Official communications]
(571) 273-8300	[After Final communications labeled "Box AF"]
(571) 273-6767	[Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to the Knox Building, Alexandria, VA.

CB
October 4, 2005

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600